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VBB on Belgian Business Law

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"Van Bael & Bellis' Belgian competition law practice [...] is a well-established force in high-stakes, reputationally-sensitive antitrust investigations."
Legal 500, 2019

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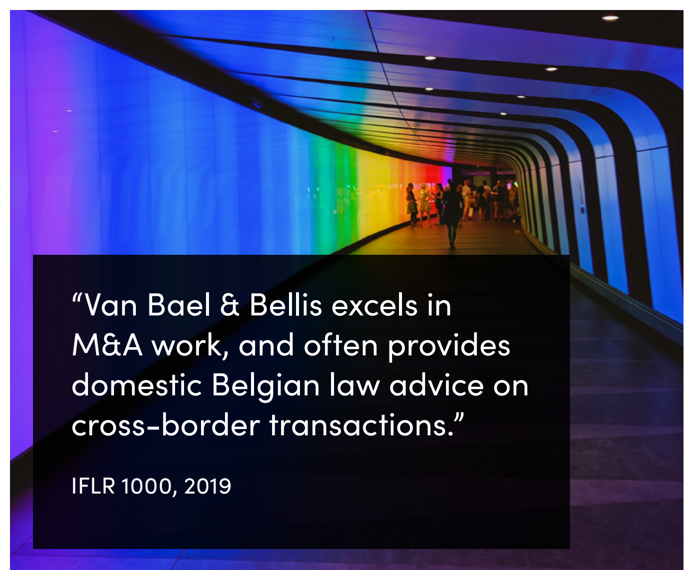

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European Commission Seeks Stakeholder Feedback on Draft Guidance and Reporting Template for Serious AI Incidents

On 26 September 2025, the European Commission (the ***Commission***) published its draft guidance (the ***Guidance***) and reporting template on serious AI incidents under the EU Artificial Intelligence Act (the ***AI Act***). The Guidance focuses exclusively on incident reporting obligations for high-risk AI systems. This initiative forms part of the Commission's effort to clarify how the AI Act's new obligations will work in practice and to align with international reporting standards. The Commission encourages stakeholders to provide feedback, including examples on the interplay with other reporting regimes, by 7 November 2025.

Scope of Consultation and Objectives

First, the reporting obligation creates an early warning system allowing market surveillance authorities to identify potentially harmful patterns or important risks of high-risk AI systems at an early stage. Second, it establishes clear accountability for providers, and to a certain extent users, ensuring they take responsibility for the proper functioning and safety of their products. Third, it enables market surveillance authorities to take timely corrective measures when incidents occur. Finally, it fosters transparency in how high-risk AI systems operate, ultimately building public trust in AI technologies through proper oversight.

The Guidance reminds stakeholders that Article 73 of the AI Act applies to serious incidents and widespread infringements of high-risk AI systems. By contrast, the Guidance does not address the obligation under Article 55(1)(c) of the AI Act to report serious incidents of general-purpose AI models with systemic risk.

Additional Definitions

The Guidance clarifies several terms that were left undefined in the AI Act. An "incident" is an unplanned or unprogrammed deviation in performance characteristics. A "malfunction" encompasses any AI system function not performing as intended or failing to uphold stated performance for its intended purpose. Examples include misclassifications, significant accuracy drops, temporary downtime, and unexpected behaviour.

The incident or malfunction must be "directly or indirectly" causal for the serious harms specified in Article 3(49) of the AI Act. Causation is established when, without the incident, the harm would not have occurred. Indirect causation includes secondary effects, such as an AI system providing incorrect medical analysis leading a physician to cause patient harm.

Categories of Harm

The Guidance clarifies each category of harm:

- "serious harm to health" includes life-threatening illness, permanent impairment, or conditions necessitating hospitalisation;
- "serious and irreversible disruption of critical infrastructure" includes destruction of key infrastructure or loss of essential records;
- "infringement of fundamental rights" covers only infringements significantly interfering with Charter-protected rights on a large scale;
- "serious harm to property" considers damage exceeding 5% of purchase price if the property cannot be used for its intended purpose; and
- "serious harm to the environment" considers baseline condition, duration, extent, and reversibility of damage.

Obligations for Different Actors

Providers of high-risk AI systems must report serious incidents to market surveillance authorities where the incident occurred. Reporting timelines vary: 15 days for most incidents, two days for widespread infringements or critical infrastructure disruption, and ten days for deaths. Providers are allowed to submit incomplete initial reports when necessary. For medical devices, reporting is limited to fundamental rights infringements.

Providers must investigate incidents without delay and must not alter the AI system in ways that may affect subsequent evaluation prior to informing authorities. They must cooperate with competent authorities, responding within 24 hours.

Deployers of high-risk AI systems must immediately (within 24 hours) inform the provider, importer or distributor, and relevant market authorities when identifying a serious incident. When deployers cannot reach the provider within 24 hours, provider obligations apply to the deployer.

Providers of general-purpose AI models with systemic risks must track, document, and report without undue delay to the AI Office relevant information about serious incidents and possible corrective measures. The Commission will publish a separate template for these providers.

Market surveillance authorities must take appropriate measures within seven days from receiving notification. National competent authorities must immediately notify the Commission of any serious incident. The AI Board may evaluate and review incident reporting.

Interplay with Other Union Incident Reporting Obligations

In accordance with Article 73(9) of the AI Act, for high-risk AI systems subject to other Union legislative instruments with equivalent reporting obligations, the notification of serious incidents will be limited to fundamental rights infringements.

This limitation applies to AI systems covered by the Critical Entities Resilience Directive (critical entities required to notify incidents disrupting essential services within 24 hours and submit a detailed report within one month), the Directive on measures for a high common level of cybersecurity across the Union ("NIS2 Directive") (essential and important entities required to notify significant incidents with early warning within 24 hours, incident notification within 72 hours, and the final report within one month), and the Digital Operational Resilience Act ("DORA") (financial entities required to report major ICT-related incidents and cyber threats).

The same limitation applies to medical devices covered by Regulations (EU) 2017/745 and (EU) 2017/746 pursuant to Article 73(10) of the AI Act. AI systems embedded in products governed by Annex I, Section B (motor vehicles, aviation, marine equipment) fall entirely outside the AI Act's reporting regime.

The Guidance acknowledges potential overlaps with the General Data Protection Regulation and the Cyber Resilience Act. The Commission will specify the interplay between incident reporting under sectoral legislation, horizontal legislation and the AI Act at a later point.

Next Steps

The Commission encourages stakeholders to provide feedback until 7 November 2025. Providers and deployers should prepare for compliance with incident reporting obligations, which will become applicable in August 2026. This preparation should include establishing internal procedures for identifying, investigating and reporting serious incidents.

The Commission's consultation publication, Guidance and incidence report can be found here.

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Minister of Economy Launches Taskforce to Strengthen E-Commerce Compliance

On 25 September 2025, the Federal Minister of Labour, Economy, and Agriculture, David Clarinval (the ***Minister***), announced the launch of an e-commerce taskforce (the ***Taskforce***) to strengthen the oversight of e-commerce practices. The initiative responds to mounting concerns over the growing influx of non-compliant goods entering Belgium via international online sales channels and the resulting risks to consumer safety and fair competition.

Background

The launch follows calls from the Central Council for Businesses (*Centrale Raad voor het Bedrijfsleven / Conseil central de l'économie*), trade unions, and consumer organisations such as *Testaankoop / Testachats*, which have raised concerns regarding the scale of low-value consignments entering Belgium from non-EU countries, particularly through platforms such as AliExpress, Shein, and Temu.

According to data cited by the Minister, nearly one billion parcels entered the EU via Belgium in 2024. A significant proportion of these imports escape effective regulatory control, and 85–95% of all products offered are estimated to be non-compliant with applicable EU rules, notably in relation to product safety, labelling, and/or environmental obligations.

These imports have raised concerns regarding market surveillance gaps, the risks to consumer health and safety, and unfair competitive advantages for third-country sellers.

Composition and Mandate of Taskforce

The Taskforce includes representatives of key federal departments and administrations, including Economy, SMEs, Finance, Digitalisation, and Consumer Protection. Its mandate is to formulate concrete measures in the following areas:

- combatting unfair commercial practices;
- strengthening the competitiveness of Belgian and EU-based businesses;
- increasing inspections of e-commerce goods entering the EU via Belgium;
- enhancing cooperation between enforcement authorities;
- ensuring that only safe and compliant products circulate in the European market; and
- making sure that non-compliant goods are withdrawn quickly from the market.

EU Measure

In addition, the Minister expressed his support for the proposal by EU Commissioner for Trade Maroš Šefčovič to introduce a EUR 2 levy on parcels valued under EUR 150 from outside the European Union. The proposal aims to address competitive distortions and strengthen customs enforcement across the internal market.

The announcement of the Minister is available in Dutch and in French.

COMPETITION LAW

Belgian Competition Authority Invites Stakeholders to Share Experience with Price Revision and Indexation Mechanisms

On 24 September 2025, the Belgian Competition Authority (*Belgische Mededingingsautoriteit / Autorité belge de la Concurrence* – ***BCA***) launched a call inviting all stakeholders – companies, sectoral organisations, consumer organisations and experts – to share their experience with price revision and indexation mechanisms. This call forms part of a broader investigation into price revision and indexation mechanisms which the BCA initiated on 6 February 2025 (*see*, this Newsletter, Volume 2025, No. 1). This investigation is expected to be completed in early 2026.

Belgian Competition Authority Investigates International Cyclists' Union Maximum Gear Ratio and Orders its Suspension

On 19 September 2025, the Belgian Competition Authority (*Belgische Mededingingsautoriteit / Autorité belge de la Concurrence* – ***BCA***) opened an inquiry into a proposed technical standard adopted by the international cyclists' union (***UCI***), to determine whether that standard distorts competition. UCI had tentatively decided that the maximum gear ratio (***Maximum Gearing***) in professional road cycling events should reflect the equivalent of a 54-tooth chainring with an 11-tooth sprocket (54×11). UCI said the Maximum Gearing was mooted for safety reasons. The test phase for this standard started on 1 August 2025 and the Maximum Gearing protocol was to apply to the Tour of Guangxi, China, between 14 and 19 October 2025.

Opening of Investigation

US based SRAM currently provides equipment to four major men's professional teams: Lidl-Trek, Movistar, Red Bull-Bora-Hansgrohe, and Visma-Lease a Bike. It challenged the Maximum Gearing protocol, arguing that it would compel the firm to make major adjustments, while several competing suppliers, such as Campagnolo of Italy and Shimano of Japan, already rely on 54×11 gearing. According to SRAM, the Maximum Gearing protocol was adopted without consultation, lacks any supporting empirical evidence, is devoid of any genuine safety justifications, puts SRAM and the SRAM-equipped professional cyclists at a competitive disadvantage, chills innovation, and distorts competition in the market for road drivetrain systems. According to SRAM, all of this gives rise to a violation of Articles 101 and 102 TFEU and Articles IV.1 and IV.2 of the Belgian Code of Economic Law (*Wetboek van Economisch Recht / Code de droit économique* – the ***CEL***).

Given the global span of this case, SRAM could have chosen the UK Competition and Markets Authority, the European Commission, or a prominent EU Member State competition authority to file its complaint. Instead, it opted for the BCA which has made a name for itself in reviewing a variety of sporting federation rules. Most recently, in August 2025, the BCA assessed the rules pertaining to football and inline hockey (*see*, this Newsletter, Volume 2025, No. 8). Additionally, in September 2022, the BCA imposed interim measures on the national regulatory association for the pigeon-racing sector with respect to its electronic registration system (*see*, this Newsletter, Volume 2022, No. 9).

Imposition of Interim Measures

SRAM not only sought a decision on the merits but also injunctive relief. On 9 October 2025, the Competition College (*Mededingingscollege / Collège de la concurrence*) of the BCA ordered UCI to suspend the implementation of the Maximum Gearing in professional road cycling events, no later than 13 October 2025 at the eve of the last race of the UCI World Tour which started on 14 October 2025 in Guangxi, China.

While the BCA did not doubt the safety goal pursued by UCI, it took issue with the way the Maximum Gearing had been adopted and the necessity of the test phase. The BCA observed that the procedures for developing

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the Maximum Gearing suffered from serious shortcomings in terms of access (due to a lack of participation of manufacturers in the development of the standard, even in the form of consultation) and transparency. The BCA noted that the criteria on which key decisions were based in the adoption of the Maximum Gearing were not documented and that UCI's explanations showed that its decision found support "solely on vague justifications with no objective basis". The BCA also identified discrimination issues, in that the Maximum Gearing specifically targets SRAM technology. Additionally, the BCA questioned the relevance of the information that could be obtained during the test phase, observing that the existing data on the frequency and severity of accidents in an environment where both transmission systems are available (Shimano and SRAM) should be much more useful.

The BCA concluded that the Maximum Gearing is *prima facie* a decision by an association of undertakings that restricts competition in breach of Article 101(1) TFEU and/or Article IV.1 CEL, without specifying whether this is an infringement by object or by effect. The BCA also found that the adoption of the Maximum Gearing without sufficient procedural safeguards constitutes, *prima facie*, an abuse of UCI's dominant position contrary to Article 102 TFEU and/or Article IV.2 CEL.

As regards the existence of a serious, imminent and nearly irreparable harm that would justify imposing interim measures, the BCA observed that Article IV.71 CEL allows it to take into account not only SRAM's harm but also that of the teams that source from SRAM, some of which had intervened in the procedure.

- The BCA found SRAM's harm to be manifest, as the restriction applies de facto only to SRAM (as acknowledged by UCI). UCI's decision may lead to the exclusion of SRAM equipment from specific cycling races, to the use of SRAM equipment offering lower performance, or force teams using SRAM drivetrains to restrict them to comply with UCI's decision. This ban and the uncertainty created by UCI are likely to permanently deter professional teams from using SRAM, even before the restriction is definitively adopted for all races. This loss of activity and capacity would go hand in hand with a loss of confidence in the brand and a knock-on effect on sponsorship and marketing in relation to SRAM's product.

- With regard to teams using SRAM equipment, the BCA found that their harm consisted of several elements, including (i) uncertainty as to the transmission mechanism the teams will be allowed to use, (ii) the risk of penalties resulting from the use of SRAM transmission on their bicycles, in accordance with UCI regulations, (iii) insofar as they restrict SRAM transmission to comply with the Maximum Gearing, the risk of failures due to the haste with which these transitional measures are implemented without prior testing, (iv) the risk of sporting and financial damage in view of the obligation to use restricted equipment, unlike other teams that do not use SRAM equipment, and (v) the risk of riders leaving teams equipped with SRAM transmission systems. This damage was likely to occur even before the definitive adoption of Maximum Gearing.

Both of these types of harm were both found to be serious and imminent. They were also difficult to repair because the sporting results of the races in which the Maximum Gearing is applied are already affected by it, and the Maximum Gearing could lead to the departure of riders from teams sponsored by SRAM and ultimately the disappearance of the latter. The BCA also found that the Maximum Gearing harmed SRAM's reputation.

The Competition College of the BCA therefore ordered UCI to immediately suspend the implementation of the Maximum Gearing (or any similar measure), either until the date on which UCI adopts a new security measure replacing the Maximum Gearing on the basis of a transparent, objective and non-discriminatory procedure, or until the case is decided on the merits. The BCA also ordered UCI to publish a press release stating that the Maximum Gearing does not apply and that there are no rules imposing maximum transmission ratios in UCI competitions.

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Comments

The BCA's decision to impose interim measures is remarkable for several reasons.

First, its effects span the globe. The BCA confirmed its competence to apply Belgian and EU competition rules even if, as in this case, the practice at stake was decided abroad, none of the parties are in Belgium and the only test race was planned in China. This is because UCI is planning other test races that could potentially take place in Belgium. Even if there were no such races in Belgium, the BCA found that at least one professional team using the SRAM products in question is based in Belgium, other professional teams likely to use these products are based in Belgium, some professional cyclists concerned are Belgian, and distributors, consumers, Belgian organisers of professional races counting on the UCI World Ranking and Europe Tour Ranking, and direct and indirect customers of SRAM in Belgium are likely to be affected.

Second, the BCA's decision protects the economic interests of economic operators (SRAM and teams using SRAM's equipment) that are found to outweigh the safety reasons claimed to be at the basis of the UCI's decision. Interestingly, the BCA did not identify any reason to doubt that, by adopting the Maximum Gearing, UCI was aiming to improve the safety of participants in cycling events. However, the BCA found no *prima facie* evidence that the test phase is necessary to establish whether a gear ratio limitation would improve rider safety. On the contrary, the BCA found that there are *prima facie* less restrictive means to establish this. As a result, the Maximum Gearing was found to be neither necessary nor proportionate.

Third, the interim measures are predicated on the existence of serious and nearly irreparable harm on the part of SRAM even though the standard was intended to apply only provisionally by way of a test. The BCA found that the uncertainty which the Maximum Gearing creates presents a real risk of SRAM products being excluded even before the restriction is definitively adopted for all races. Although temporary, the standard was therefore found to have, or to be likely to have, permanent effects.

Belgian Competition Authority Issues Opinion on Portability of Bank Account Numbers

On 15 September 2025, the Belgian Competition Authority (*Belgische Mededingingsautoriteit / Autorité belge de la Concurrence* – ***BCA***) published an opinion (the ***Opinion***) on Private Members' Bill 55K0223 of 16 September 2024 aiming to facilitate switching banks (*Wetsvoorstel tot wijziging van het Wetboek van Economisch Recht, met het oog op de invoering van een systeem om de overdracht van het internationaal bankrekeningnummer (IBAN) daadwerkelijk mogelijk te maken / Proposition de loi modifiant le Code de droit économique, instaurant un réel système de portabilité des numéros IBAN des comptes bancaires* – the ***Bill***).

The Bill includes three parts:

- It introduces a system of bank account number portability (via the IBAN identifier).
- It ensures that customers retain the full history of transactions made to and from that account even after switching to another bank.
- It extends the existing account switching service on payment accounts to regulated savings accounts.

The BCA has previously examined the banking sector. More specifically, on 31 October 2023 the BCA published a report (the ***2023 Report***), in which it pointed to several shortcomings, including deficiencies in the system for switching accounts that affect the competitive behaviour of banks (*see*, this Newsletter, Volume 2023, No. 12).

While focused on the Bill, this new Opinion gives the BCA the opportunity to provide an update of its 2023 findings.

IBAN Portability and Transfer of Full History of Transactions

In its Opinion, the BCA notes that, in 2023, it recommended conducting a study on the feasibility and costs of introducing a system of IBAN portability in Belgium. This is because a report by the European

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Commission had concluded that portability at EU level would not be economically viable as the implementation costs were expected to exceed the benefits.

The BCA reaches a similar conclusion regarding Belgium, noting that IBAN portability would create several problems.

- First, the existing IBAN system links each IBAN number to a specific bank via the BIC code, which an IBAN portability system would compromise.
- Second, the proposed portability system might not comply with Directive 2014/92/EU on the comparability of fees related to payment accounts, payment account switching, and access to payment accounts with basic features (which regulates the circulation of payments in Europe) and with SEPA regulations.
- Third, it would become more difficult for banks to draw up their balance sheets, due to the lack of association between the assets and liabilities of the IBAN number within the bank at the end of the year.
- Fourth, implementing the system would require overcoming technical difficulties and would be costly, and these costs might be passed on to consumers.

Additionally, the BCA doubts that introducing this measure would have a significant impact on banking mobility, notably due to the concentration of the Belgian market, growing competition from fintech firms offering products that are not based on the IBAN system, the inertia of Belgian consumers, and the absence of a genuine EU banking area which limits competition from banks from other Member States.

Extension of Portability Rules to Regulated Savings Accounts

The existing account switching service (the ***Service***) is currently limited to payment accounts. It allows consumers to switch banks by filling out a form requesting their new bank to transfer their payment orders and/or close their account with their old bank.

The BCA notes that this would simplify the switch for consumers, increase the number of consumers who can benefit from it (as this Service is currently applied to regulated savings accounts on a voluntary basis only, by most but not all banks), increase competition within the retail banking market (since regulated saving accounts are mainly held by small savers and are the most popular savings products in Belgium), and enhance the effectiveness of the existing Service, as many banks link payment accounts to regulated savings accounts.

However, the BCA also observes possible downsides to this measure. In its view, limiting the extension of the Service to regulated savings accounts could increase the existing tax discrimination between various savings products in favour of the regulated savings accounts. The BCA also considers that the measure will have a limited impact on consumer interbank mobility as the issues which it identified in the 2023 Report (such as bundled sales and loss of loyalty bonus when changing banks) still exist. The practice of banks to limit withdrawals from regulated savings accounts to transfers to an internal bank payment account may also continue discouraging consumers from switching banks, as the consumer must keep a payment account with the bank with which it has its regulated savings account.

Alternative Competition-enhancing Measures

While the BCA supports the objective of strengthening competition in the retail banking market, it considers that the Bill could be difficult to implement and have limited effect. According to the BCA, easier measures that are more likely to increase competition include (i) limiting bundled sales, (ii) integrating the loyalty bonus into the base rate for regulated savings accounts, and (iii) promoting other savings instruments.

As it was submitted by members of an opposition party, this Bill is unlikely to become law in its current form. However, the governmental agreement of 31 January 2025 makes clear that increasing competition in banking and insurance and boosting customer mobility is also a priority of the current federal government (*see*, this Newsletter, Volume 2025, No. 2).

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Belgian Competition Authority Publishes Guidelines Regarding Exchange of Information for Reimbursement of Combination Therapies

On 11 September 2025, the Belgian Competition Authority (*Belgische Mededingingsautoriteit / Autorité belge de la Concurrence* – ***BCA***) published guidelines for pharmaceutical firms that seek to exchange information for the purposes of applying for the reimbursement of a combination therapy (***CT***) of pharmaceuticals whose marketing authorisations are in different hands (the ***Guidelines***).

A CT is a treatment relying on two or more medicines and/or medical devices in one combined treatment schedule to treat a single disease. CTs that consist of two pharmaceuticals are able to target multiple pathways of a disease simultaneously and may exhibit greater clinical efficacy than a single treatment when its component treatments have complementary, additive, or synergistic pharmacodynamic effects. Their importance has grown significantly in a range of therapeutic areas, including oncology.

The BCA has now outlined the principles that should facilitate limited forms of cooperation between firms that own marketing authorisations for medicines that form part of a CT. The Guidelines only cover the exchange of information and list data sets that can be exchanged among pharmaceutical firms (§ 31) and sets of information that should not be shared (§ 32). According to the Guidelines, the first category of data includes matters such as:

- epidemiological data (incidence of disease; presumable number of patients);
- patient-level data;
- therapeutic value of the CT resulting from the data generated by clinical data;
- budgetary impact of a possible reimbursement arrangement if based on publicly available *ex-factory* price.

By contrast, the second category of information that remains off-limits for an exchange includes:

- data concerning the net price, as well as the gross and net margins of the components of the CT;
- cost structure of the participating firms;
- information regarding the attribution of the therapeutic value to the various components of the CT;
- budgetary impact on medicine budget and overall healthcare budget.

The Guidelines also recommend the creation of a dedicated "clean" team that is responsible for implementing and monitoring the reimbursement procedure and maintaining the confidentiality of business secrets (§§ 34 and following).

The scope of the Guidelines is limited to the exchange of information and does not address other issues such as pricing arrangements between actual or potential competitors, a matter tackled by the UK Competition and Markets Authority in its advice regarding combination practices which it published in November 2023 (*see*, Van Bael & Bellis Life Sciences News and Insights of 21 November 2023). Additionally, the Guidelines seem premised on the relationship between actual or potential competitors. The scope for cooperation between firms that do not compete and have no intention to compete in the relevant therapeutic areas should be larger.

Lastly, the BCA did well to specify that, from a competition law perspective, firms retain their autonomy and have the ability to withdraw from a pending procedure involving inter-firm cooperation at any time (§ 37).

FOREIGN DIRECT INVESTMENT

Second Annual Report on Belgian Foreign Direct Investment Screening Published

On 12 September 2025, the Federal Public Service Economy (*Federale Overheidsdienst Economie / Service Public Fédéral Économie*) published its second annual report (the ***Report***) on the screening of foreign direct investments (***FDI***) and the operations of the Belgian Interfederal Screening Committee (*Interfederale Screeningscommissie / Comité de Filtrage Interfédéral* – the ***ISC***). The Report covers the period of 1 July 2024 to 30 June 2025, comprising the second year of implementation of the Belgian FDI screening mechanism. While it is still early to draw definite conclusions based on a comparison of the Report against the first annual report published in 2024 (*see*, this Newsletter, Volume 2024, No. 9), the Report seems to reveal incipient trends and offer valuable insights into the evolution of the implementation of the Belgian FDI screening mechanism.

Clean Record Continues, but Figures Suggest More Mature ISC

The Report shows that the procedure has continued to run smoothly for most notifications with only few delays and, so far, no blocking decisions.

Between 1 July 2024 and 30 June 2025, the ISC handled 100 notifications, reflecting a significant increase over the 68 notifications recorded last year. 89 of those notifications have been approved without any accompanying measures, while 8 were still pending on 30 June 2025.

Just like last year, only five notifications entered into a second in-depth screening phase. Three of these notified investments have already been cleared, two of them without mitigating measures (and requiring on average 49 days to be processed). Two cases remain under review.

Importantly, for the first time investments have been made subject to mitigating measures. In one case, these included:

- placing specific technology, source code and/or know-how in the custody of a third party in Belgium;
- guarantees to ensure the continuity of defined processes; and
- the appointment of compliance officers.

In addition, while the Report confirms that again no notified investments were rejected, it reveals that over the covered period two notifications ended up being withdrawn.

Unlike last year, the ISC has not opened any *ex officio* investigations. Interestingly, however, the ISC has proactively launched 16 inquiries into non-notified investments, requesting information with a view to determining whether these should have been notified. Unfortunately, the Report does not indicate if these inquiries resulted in a subsequent "voluntary" notification.

Overall, these figures reveal a more active screening approach under the control of a more experienced ISC. Not only are many more investments being notified, the ISC is adopting a more targeted approach by opening relatively less in-depth reviews, but more often entering into negotiations on mitigating measures. The ISC's proactive inquiries into non-notified investments also display a more active policing of the market.

Timing

During the second year of implementation, notifications continued being accepted in a short time period. The first phase review files were on average closed in 31 days, just like last year.

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The Report again shows the importance of filing a complete notification. In 85% of cases, the ISC was able to immediately accept a complete filing. This marks a significant increase over last year's 44% and suggests that investors and the ISC have become more experienced in submitting complete filings and quickly assessing their completeness. However, in 15% of cases information was missing from the initial submission, preventing the ISC from accepting the filing and causing an average acceptance delay of two days. 7 notifications received requests for additional information during the notification process, marking an increase from 4 such requests last year. These figures suggest that in the cases in which an initial filing was considered incomplete, or additional information was requested at a later stage, the procedure faced a more significant delay.

The Report also emphasises the importance of the role of the Coordination Committee on Intelligence and Security (*Coördinatiecomité Inlichtingen en Veiligheid / Comité de coordination du renseignement et de la sécurité* – the ***CCIS***). The CCIS plays a key role establishing a link between the FDI screening mechanism and the Belgian intelligence, security, cybersecurity, and crisis management services, as well as the Ministries of Defence, Foreign Affairs and Justice. Its main role is to assess the risks for national security, public order, and strategic interests. The CCIS has 25 days to issue its opinion, subject to exceptions, which the Report indicates remain rare (less than 10% of notifications).

Data, Digital Infrastructure, and Health Remain Most Screened Sectors

The sectors most targeted by the notifications involved sensitive information / personal data (21%), digital infrastructure (14%), energy (13%), healthcare (12%), and dual use (9%).

While notifiable acquisitions fall in a range between investments conferring control and stakes of only 25% (or in some cases even 10%) of voting rights), the Report indicates that the large majority of notifications (91%) involved acquisitions of control. In addition, most notified investments concerned transactions in which the Belgian target formed part of a larger acquisition, with just 22% of notified investments concerning transactions in which one or more Belgian entities were the principal target.

Furthermore, 22 notifications were presented as internal restructurings, which amounts to a 100% increase over last year, with 8 of these not resulting in a new ultimate beneficial owner. This again calls into question the added value of the requirement to notify genuine internal restructurings which do not result in a change of ultimate beneficial owner.

US and UK Investors Remain Predominant

The majority of the notified investments still originate from the United States, accounting for 45% of the notifications, followed by the UK, with 22% (compared to respectively 43.4% and 29% last year). Other investor countries of origin lag far behind, with Japan (8), Canada (7) and China (5) accounting for far fewer notifications.

Outlook

The Report again refers to the ongoing revision of the EU FDI Regulation, which will make screening mandatory in all Member States, harmonise the scope of application of the rules, strengthen cooperation and align national procedures (*see*, this Newsletter, Volume 2025, No. 5). The European Commission is expected to provide an update of the negotiations between the EU institutions in the second half of October 2025.

The Report is available here in Dutch, English, and French.

INTELLECTUAL PROPERTY

Brussels Enterprise Court Dismisses Trade Mark Infringement Claim Because of Older Marketing Authorisation for Medicinal Product

On 18 September 2025, the President of the Dutch-language Enterprise Court of Brussels delivered a judgment in *Huvepharma v. EMDOKA* holding that a marketing authorisation qualifies as an earlier right restricting the exclusive rights of a holder of a later European Union trade mark (***EUTM***).

In the case at hand, the contested EUTM "DOXORAL" was filed on 2 March 2012 by InVivo NSA SA and registered on 21 June 2012 for "veterinary medicines" (Class 5). Following a transfer of the trade mark to Neovia SA, Huvepharma acquired that firm, including the EUTM "DOXORAL", on 1 October 2018.

EMDOKA, a Belgian veterinary pharmaceutical company, has been commercialising its product "DOXYRAL" in Belgium for over 25 years pursuant to marketing authorisations issued by the Federal Agency for Medicines and Health Products (*Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten / Agence fédérale des médicaments et des produits de santé* - the ***FAMHP***). The name "DOXYRAL" is a combination of a prefix referring to the active ingredient doxycycline and a suffix referring to the oral administration of the product.

On 4 November 2021, EMDOKA filed "DOXYRAL" as a Benelux word mark. Huvepharma objected to the application before the Benelux Office for Intellectual Property (the ***BOIP***), which upheld the opposition pursuant to Article 2.2ter(1)(b) of the Benelux Convention on Intellectual Property (***BCOIP***) and therefore refused the registration of "DOXYRAL". On 8 December 2022, EMDOKA also sought the invalidity of "DOXORAL" before the European Union Intellectual Property Office (***EUIPO***), arguing descriptiveness and lack of distinctiveness. The EUIPO dismissed the claims of EMDOKA. Despite these decisions, EMDOKA continued to offer its product under the name "DOXYRAL" on the Belgian market. Huvepharma then brought an infringement action before the President of the Dutch-language Brussels Enterprise Court, seeking a cease-and-desist injunction with respect to EMDOKA's continued use of "DOXYRAL".

The President first examined EMDOKA's counterclaim that sought to have the trade mark "DOXORAL" declared invalid because it lacks distinctive character and is descriptive. In this regard, she first noted that Huvepharma's argument that the invalidity claim expired in accordance with Article 2262*bis*, §1 of the Belgian Civil Code cannot succeed because such a claim is not subject to a statute of limitations. The President confirmed the principle of EU trade mark law that a trade mark can only exist if it satisfies the fundamental principles of registration. As a result, a trade mark that was erroneously registered can be challenged at any time. Unlike the relative grounds for invalidity, Regulation 2017/1001 of 14 June 2017 on the European Union trade mark (***EUTMR***) does not impose any time limit to bring such a claim based on an absolute ground for invalidity.

The President further noted that the decisions of the BOIP and the EUIPO do not have the force of *res judicata* as these decisions are mere administrative decisions with a different object and legal basis. Additionally, the fact that EMDOKA did not appeal the decision of the BOIP does not mean that that party waived its right to later challenge the validity of a registered trade mark before the competent court. In this respect, the President interestingly made the distinction that the counterclaim seeking invalidity aims to obtain the invalidity of the trade mark "DOXORAL" because it lacks distinctive character while the opposition aims at assessing whether there is a likelihood of confusion between a trade mark and the sign subject to the registration application. The President concluded that the invalidity action had broader aims, namely clearing the trade mark register from erroneously registered trade marks and preserving the free use of descriptive signs.

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Finally, the President assessed whether the trade mark "DOXORAL" should be declared invalid because of a lack of distinctive character and descriptiveness. She rejected the counter-claim and concluded that the trade mark had sufficient distinctive character.

As regards the main claim, the President assessed whether EMDOKA could rely on its marketing authorisation for its product "DOXYRAL" as an earlier right within the meaning of Article 138 EUTMR. According to the President, the name of veterinary medicines is assessed and approved by the competent authorities in the context of marketing authorisation procedures and is binding with respect to the packaging, the package leaflet, the summary of the product characteristics and the entire distribution chain. As a result, the marketing authorisation not only creates obligations, but also a public-law structured legal status. Without this authorisation, the product cannot be placed on the market. The authorisation therefore confers both obligations and rights, including the right to use the product name in a regulated distribution system. EU trade mark law is without prejudice to the requirements in this regulated market. Referring to *Classic Coach Company*, a judgment delivered in case C - 112/21 by the Court of Justice of the European Union, the President also noted that the notion of "earlier right" is not limited to classic IP rights, but also extends to other earlier lawfully created positions and situations of third parties. The President concluded that the right to market a veterinary medicine under its approved name is a legally enforceable right arising from public law regulation. The Court also emphasised the public interest in stability of product names in the pharmaceutical sector. Physicians, pharmacists, and patients must be able to rely on consistent and unambiguous product names to ensure patient safety, prescription accuracy, and pharmacovigilance. Prohibiting the use of a long-established, authorised product name would undermine these objectives and risk confusion in medical practice. Finding that EMDOKA's marketing authorisation for its product "DOXYRAL" constitutes an earlier right with respect to the marketing of that product in the Belgian market, the President rejected Huvepharma's infringement claim.

This judgment offers interesting perspectives with respect to the relationship between national law and EU trade mark law and the relationship between administrative proceedings before the BOIP and the EUIPO and subsequent legal proceedings before the competent national court in the context of invalidity claims. The judgment confirms that earlier public law authorisations are capable of limiting the scope of protection normally afforded by later trade mark rights, and that intellectual property rights are without prejudice to an earlier public-law structured legal status.

General Court Annuls EUIPO Decision On Sound Mark

On 10 September 2025, the General Court (***GC***) annulled a decision of the Fifth Board of Appeal (***BoA***) of the European Union Intellectual Property Office (***EUIPO***) in a case between Berliner Verkehrsbetriebe (***BVG***) and the EUIPO regarding the registrability of a sound mark under Article 7(1)(b) of Regulation (EU) 2017/1001 of 14 June 2017 on the European Union trade mark (***EUTMR***).

Background

The dispute arose in March 2023 when BVG applied to register, as an EU trade mark, a short melody consisting of four perceptible sounds for services in Class 39, including "transport; passenger transport; wrapping and packaging services; storage; arranging of transportation for travel tours". The sound of the melody is accessible here. The examiner refused registration finding that the sound lacked distinctive character. EUIPO's BoA upheld the refusal concluding that the melody was "so short and banal" that it could not be recognised by consumers as an indicator of the commercial origin of the services which it represented. BVG challenged that decision before the GC, arguing that the melody had a distinctive character consistent with EUIPO's own guidelines and practice on sound marks.

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GC judgment

The GC first observed that a minimum degree of distinctive character is sufficient to cause the absolute ground for refusal set out in Article 7(1)(b) EUTMR to be inapplicable and that the criteria for assessing distinctiveness apply equally to all types of trade marks, including sound marks. In addition, a sound mark must have a certain "resonance" enabling the relevant public to perceive it as a trade mark and not as a functional element or an indicator without any inherent characteristics.

As regards the BoA's decision, the GC noted that it has previously been held that a sound sign which is characterised by excessive simplicity and is no more than the mere repetition of two identical notes – in that case a sound akin to a telephone ringtone – was not capable of conveying a message that could be remembered by consumers. However, the GC agreed with BVG that several factors should be taken into account when assessing whether a sound mark has distinctive character. As such, the GC noted that short jingles are commonly used in the transport sector to create a recognisable sound identity and create the audio equivalent of the visual identity of a mark, for the goods and services associated with it. The GC further noted that the melody at issue, consisting of four different perceptible sounds, does not have a direct link with the services covered (*e.g.*, the sound of a passing metro or train, or the sound of an aircraft taking off) and had no direct descriptive link with the services concerned. Similarly, the GC held that it has not been established that the sound of the melody of which the trade mark applied for consists of is already known to the public. The GC agreed with BVG that it may be considered that the purpose of the sound of the melody is rather to serve as a jingle, *i.e.*, a short, striking sound sequence likely to be remembered. The GC further highlighted that the EUIPO itself has accepted comparable short melodies in the past, such as the sound marks registered by Deutsche Bahn and Flughafen München. It further noted that the EUIPO Examination Guidelines contain examples of similarly short sequences accepted as distinctive.

The GC therefore concluded that the BoA did not correctly assess the distinctive character of the mark and that the melody was capable of distinguishing BVG's services and therefore possessed the minimum degree of distinctive character required under Article 7(1)(b) EUTMR.

In conclusion, the judgment confirmed that brevity and simplicity do not in themselves prevent a sound mark from being distinctive. This reasoning may be extended to other types of trade marks. The fact that a trade mark is simple or banal does not, by itself, amount to a lack of distinctive character.

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